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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003904278 for a patent by THOMAS J BORODY as filed on 13 August 2003.



WITNESS my hand this
Nineteenth day of August 2004

J. Billingsley

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IMPROVED ORAL OXYGENATING APPLIANCE

Technical Field

This invention relates to the field of medical appliances which are used to keep the mouth of patients open for lengthy periods during medical or surgical procedures such as endoscopy. More particularly the invention relates to an appliance annular or tubular in nature intended to permit the patient to breathe through the mouth whilst fitted with the appliance.

Background Art

The oral medical appliance which is typical of the kind to which the invention relates is the endoscopic mouth guard or 'bite block'. A variety of devices have been previously used for controlling the communication of gas entering and leaving the respiratory system. However, the majority of these relate to the administration of anaesthetic agents rather than to the carrying out of an oxygenated endoscopic procedure. A number of such mouth pieces have previously been described including those of US Patent No 1,050,620 of De Ford, US Pat. No 1,592,345 of Drager, US Pat No 2,521,084 of Oberto, and US Pat.No 3,207,154 of Rubilotta. These have generally described mouth pieces for introduction into the mouth helping to seal the mouth so as to provide various gases for anaesthesia focusing especially on obtaining an airtight seal. Such inventions however were directed away from the current invention in that they were not designed to allow the patient to maintain oxygenation while the patient is being investigated with a diagnostic instrument such as an endoscope to pass through the mouth piece.

The current invention is directed generally to mouth guards and more specifically to disposable mouth guards for use with diagnostic instruments such as an endoscope. Green et al in US Pat No. 4,640 273 in 1987 described a disposable mouth guard constructed of relatively hard rigid core to allow the patient to bite down on the mouthguard and yet allow an endoscope to pass through the mouth. The inventive aspect of this mouthguard was that it had a relatively flexible soft coat to cushion the patient's bite. However, this mouth guard was not molded to the natural shapes of the teeth and bite, and was rather a tubular or annular piece, placing the greatest strain on the incisor teeth.

In the use of medical diagnostic instruments of the endoscope type a mouthguard is inserted into the patient's mouth and the barrel of the endoscope is inserted through the central opening of the bite block. Without the presence of the bite block the patient would tend to bite down on the endoscope with likelihood of causing damage to the internal components of the instrument and also hurting themselves. While the mouthguard achieved the desirable

result for protecting the instrument it was noted that patients who undergo endoscopic procedure under sedation frequently underwent hypoxia, that is to say an undesirable fall in the oxygen saturation level in the blood. The level of hypoxia can be minor and was generally deemed to be generally tolerable in young patients. On the other hand it is frequently quite profound especially in the now more frequently seen elderly patients and those with respiratory and cardiovascular disorders. In such patients with compromised circulatory or pulmonary systems the hypoxia induced by sedation and obstruction of the mouth with a bite block can and has precipitated cardiac or respiratory arrest. Furthermore, the lowered oxygen tension may delay recovery from sedation/anaesthesia. Thus, although oral medical appliances of the kind described here (called mouthguards or bite blocks) are normally annular or tubular so the patient can breathe through the open mouthpiece, there is generally a need to administer oxygen to the patient when fitted with such a bite block.

US Pat. No 5,273,032 by Borody in 1993 describes the combination of an oral medical appliance of the bite block with an oxygenating system. This was achieved by fitting the bite block with tunnels within the bite block pointing both at the nostrils and internally into the patients mouth to allow continuous insufflation of oxygen so as to maintain patient vascular oxygenation. The invention therefore achieved the object of provision of an oral appliance of the kind in question together with a supplementary stream of oxygen into the patient's airways. Not only was the stream of oxygen directed towards the patients mouth but it was also directed to the patients nostrils. This invention was a major step forwards in endoscopic oxygenation in that it prevented numerous cases of hypoxia and cardio / respiratory arrest in clinical practice where endoscopy is carried out numerous times per day world-wide.

Later, Weaver (US Pat No. 5,413,095) also described an invention whereby oxygenation could be achieved by tunnels in the bite block pumping oxygen into the patients mouth. The novel aspect of this invention was that the mouthpiece provided auxiliary opening through which fingers could be inserted into the patient's mouth so as to allow for manual manipulation of the mouthpiece once it was placed in the mouth. This invention however did not help in patient's oxygenation but rather assisted in insertion of fingers and furthermore, it provided no oxygenation to the nose. Jackson in US Pat. No. 5,513,634, described a standard bite block to which was attached oxygenating flexible nasal prongs extending upwards from the manifold into the patients nostrils to supply supplementary gas separately from air breathed through the patients mouth. The major disadvantages here were that there were no tunnels of oxygen pumping gas into the patients mouth – an important oxygen entry during sedation. Furthermore, the nasal prongs prodded the patient in the nose and this was uncomfortable to patients given that nostril oxygen delivery was achieved by long plastic

projections into the patients nostrils. The other unfortunate disadvantage of Jackson's invention was that the clip-on portion of the cannula was unable to be connected to the patients head once the patient left the endoscopy room and it could not be used to oxygenate the patient while they were recovering from endoscopy.

Goldstein in US Pat.No 5,752,520 in 1998 described a complex oxygenating device to alleviate a variety of breathing disorders having a mouldable mouthpiece clamped between upper and lower teeth. However, this is not a device that can be used during endoscopy as it has no opening to allow the entry of the endoscope, and is more a general device to oxygenate patients who are severely ill.

In the field of patient oxygenation during and after endoscopic procedures - a very common and rapidly growing field - there now exists a need for an efficient oxygenating bite block which can be fitted with a disposable oxygenating device that can be taken into the recovery and which will not only oxygenate the nose but will also continue oxygenating the mouth in patients who, following sedation, continue to sleep, snore, and inhale both from the nose and the mouth. Current endoscopic technology uses either a non-oxygenating or an oxygenating bite block during endoscopy and then, when patients are taken to the recovery room standard nasal prongs are fitted to the patient with a strap or tubing around the back of the head and the patients oxygen is delivered through the nose. Unfortunately, over 60% of patients will initially - from our surveys - breathe through the mouth in post-endoscopic recovery - and hence nasal prongs deliver little oxygen to where it is most needed. Nasal and oral oxygenation is crucial.

The current invention describes a standard oxygenating bite block which is combined with a detachable, recovery room oxygenating nasal delivery system which at the same time insufflates oxygen downwards from the upper lip onto the patients mouth so oxygenating both orifices - one or both of which are being used during recovery - so as to raise the patients depressed oxygen tension, so preventing cardio / respiratory arrest.

In another form of the invention the flat oro/nasal oxygen delivery system can be manufactured and used without the bite block, but as a 'standalone', light, cheap, non-irritating, postoperative oro/nasal oxygenating device.

Another issue with current bite blocks is the fact that the current bite blocks have not been shaped to meet the 'unique' shape of the patients "average mouth". They are tubular or annular structures and patient's mouth/teeth are semi circular and have both a tooth and a lip

area. The current mouth guard/bite block is so designed as to better fit the patients mouth so as to prevent damage to teeth/dentures which on occasions occurs during endoscopy and in particular during the removal of the endoscopic mouth piece. Another current approach to oxygen delivery to a patient in recovery employs an oxygen-delivery tube with tubular open-ended nasal prongs or cannula at the end of a delivery tube for insertion in the patient's nasal passages. The disadvantages of such nasal cannulae include most commonly the fact that the patient may not be a nose breather, that the patient can develop nose bleeds from the dryness of the nasal canal, and that the patient may find the front of the oxygen cord hanging down directly in front of the patient causing downward pressure on the ears where it is suspended.

The final and recurrent problem with available bite blocks is the rather small, though standard size oral opening which fails to admit – during esophageal dilatation – of a large dilator (Fr 60; 20mm). In fact during a dilatation procedure when the large dilator is passed the physician needs to remove the bite block and insert an alternate obturator, eg a large syringe – and then proceed with the dilatation.

Disclosure of Invention

The object of the present invention is to overcome the deficiencies of prior art as listed above.

- A. The new invention achieves a new standard in bite block / oral fit by building a product moulded to the patients mouth using dental technology. This results in an unobtrusive, fitted oral bite block moulded to fit an "average mouth shape". The new shape permits the use of soft liner or fillers along the tooth groves to protect teeth or dentures. This is distinct from the tubular liner un-fitted to the tooth line as described by Green et al in Pat No 4,640,273. These liners can be made in various flavours for patient comfort, but also as a means of ensuring they are discarded after each use, as cleaning may not remove saliva and could also leave behind irregular, tattered liner remainders which would look rough and 'used'.
- B. Secondly, the bite block now combines an extended nasal delivery system which is fitted above the mouth piece and fits to the nasal outline. This can be completely attached to the mouth piece or can be clipped on allowing it to be manually disconnected. The new device delivers oxygen both to the nose and through tunnels posteriorly through the bite block into the mouth. In this way during endoscopy entry of oxygen to both the nasal and oral cavities is assured similar to that described in Borody US Pat No. 5,273,032. The annular or tubular moulded body of the bite block adapted to the patient's mouth shape extends above the upper lip towards a broad, flat hollow plate within which are tunnels

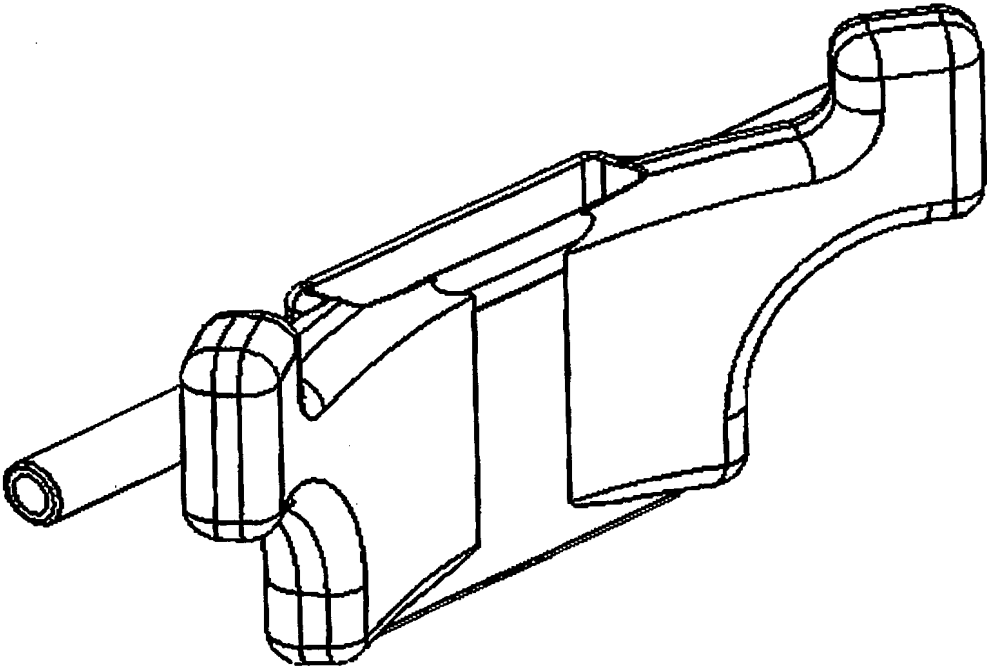
directed upwards at the patients nostrils. Furthermore, this flat piece is held in place to prevent lateral movement by extended wings on each side of the lower nose and has strap attachments laterally and carries an oxygen port - which in the previous model was attached to the body of the bite block. The tunnels delivering the oxygen to the nostrils end flush with the plate under the nose and do not end in nasal prongs to irritate or cause bleeding within the patients nose (cf. the impractical protruding nasal rods described by Jackson - US Patent 5,513,634). Following endoscopy, the flat piece - to which the strapping or oxygen tubing is attached so it can be carried to the recovery room - is removed either by the anaesthetist by flexing it back and forth along pre-designed breakage point or un-clipping it depending on the model. Upon breaking off / removing the flat oxygenating piece at the top of the front lip section, the bite block part, having been removed from the mouth is discarded and the patient is taken into the recovery room with the flat nasal piece insufflating air not only into the patients nose (see Jackson - US Patent 5,513,634) but also downwards over the lip into the patients mouth, since the patient will now be capable of breathing either through the mouth - generally - or through the nose.

- C. As a further invention , the flat oro / nasal piece normally detached from the bite block after endoscopy can also be manufactured as a stand-alone product for simple, cheap, and comfortable oxygenation to replace the currently-used nasal prongs. This has utility in emergency room or in post-operative situations and improves on the current nasal-prongs in that it supplies oxygen to both the nose and mouth and does not irritate the nasal mucosa. It can be held in place by a flexible strap around the patients head. It can also be held in place by oxygen tubing emanating from each end of the nasal piece(or by both means), reaching over each ear, then coming together under the patients chin and can be tightened with a sliding ring over each tubing.
- D. A further aspect of the invention is to match the bite block with available esophageal dilator diameters. In this novel bite block, the internal insertion diameter of the annular section, the insertion diameter will marginally exceed 20mm to permit the entry of the 60Fr dilator.
- E. Yet a further aspect of the invention is the inclusion in the design of a curved 'snap-in' plastic open-tube obturator through the central opening of the bite block to depress the tongue and open the airway with access to the pharynx for suction purposes. The plastic central device can be a rounded, slightly bent either flat or tubular device. It is designed to

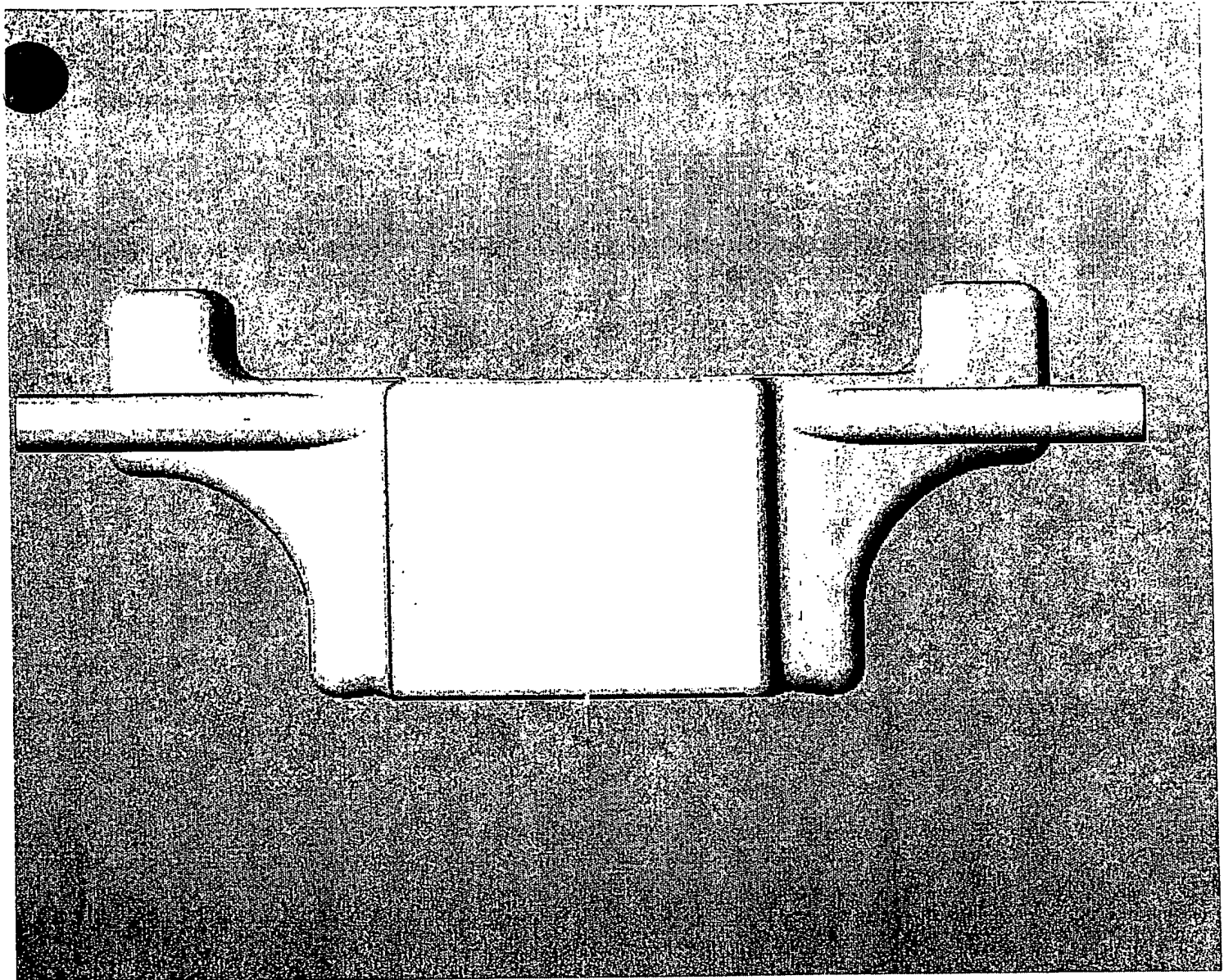
depress the tongue and open the oral cavity to permit suction with eg a Yankaeur sucking device or similar apparatus. This 'snap-in' device can resemble a Guedel airway and indeed can function in the same way, permitting for ready mask-assisted ventilation of the occasional patient who might not breathe up well during sedation. Such an 'add-on' device to this novel oxygenating bite-block will permit for urgent ventilation or suction without needing to take out the bite-block – a difficult task to achieve in sedated patients.

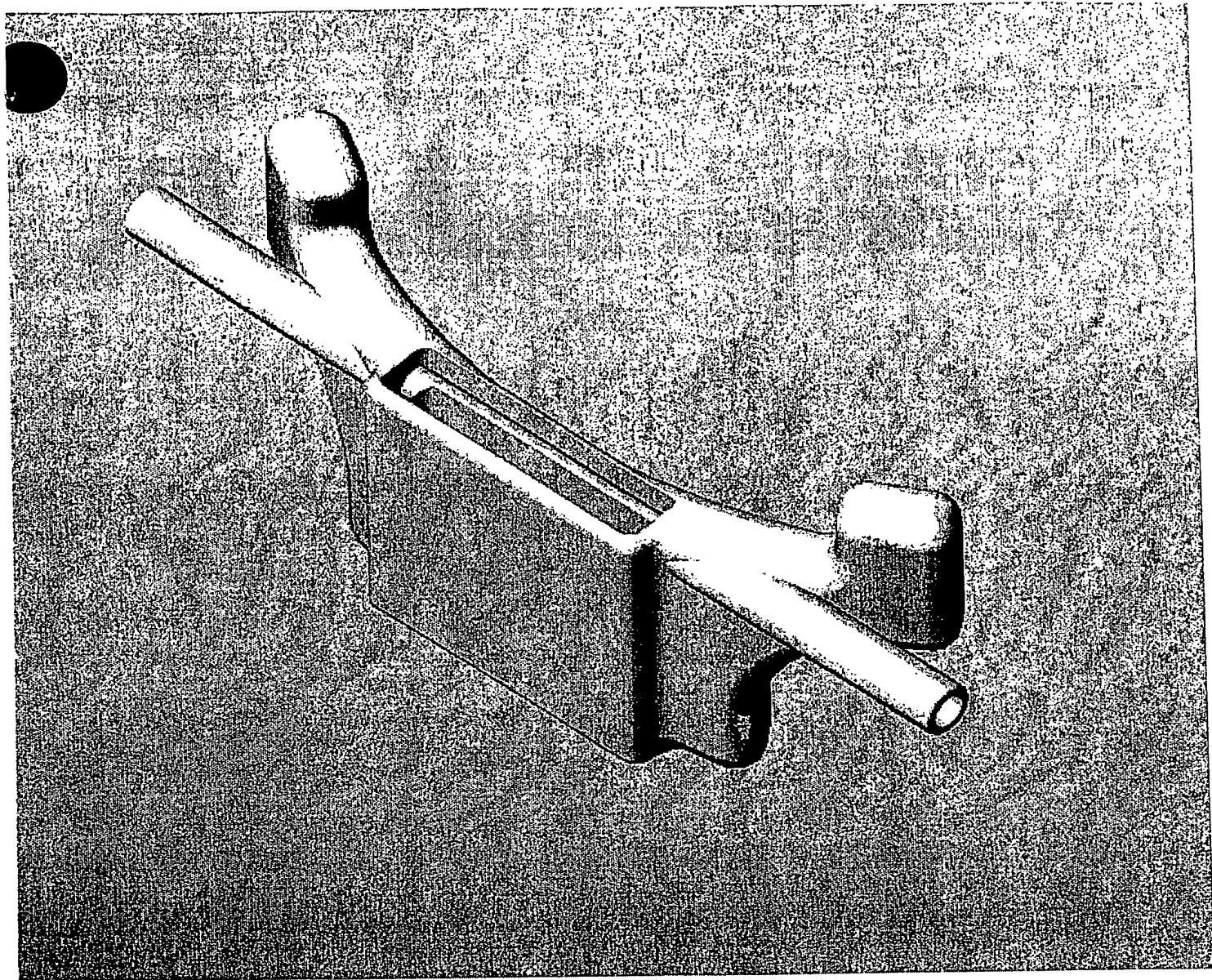

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THOMAS J BORODY

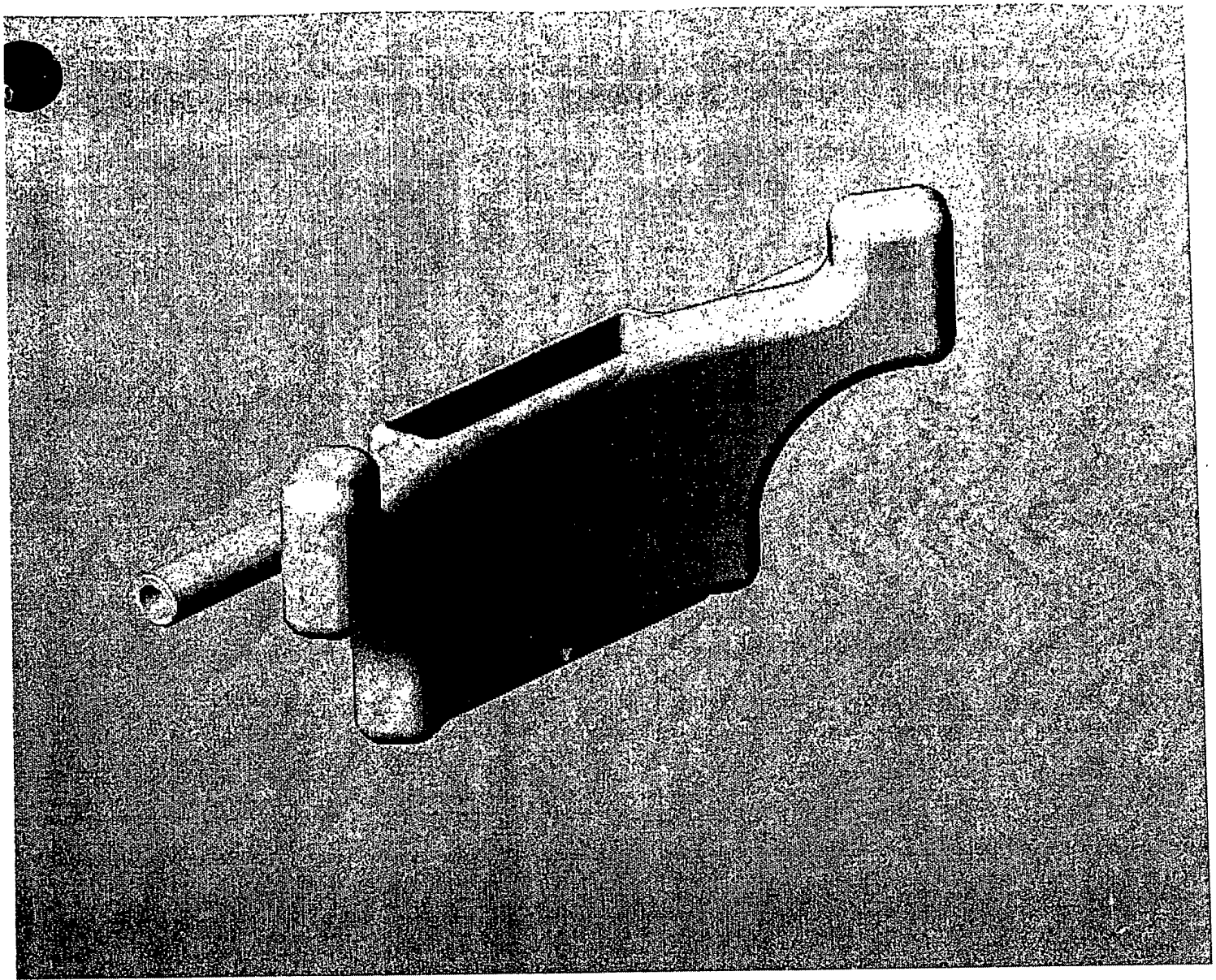
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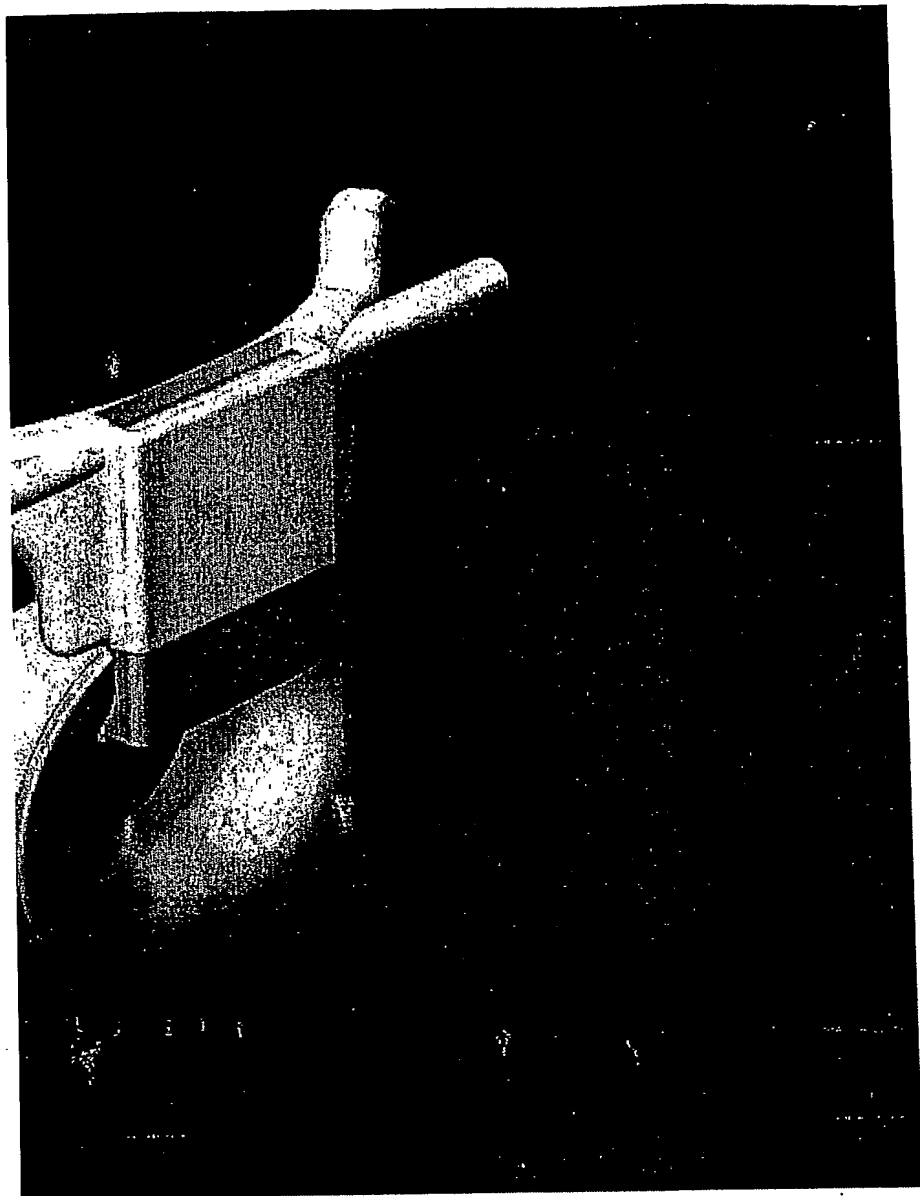


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